Knowledge Acquisition Session Report
NCI DCP – Protocol Information Office

Session Date: August 29, 2000 **Session Time:** 1:00 – 3:00 PM

Session Topic: Division of Cancer Prevention Information Needs

Knowledge Analysts: Lisa Chatterjee, Christina Schriver, Oracle; Bill McCurry, Robert Harding, ScenPro, Inc.

Organization: Protocol Information Office, NCI Division of Cancer Prevention

Session Location: Office of Informatics Conference Room, Rockville, MD

Type of Session:

_X___Interview _____ Task Analysis _____ Scenario Analysis
____ Concept Analysis _____ Observation _____ Structured Interview
_____ Other:

Documentation: RD.070 Detailed Business Function Model, KA Report

General Topic Area

DCP funding and patient accrual procedures

Session Goals

To discuss the different funding sources used in DCP studies and to discuss patient accrual issues with domain experts

Report Summary

The CCOP (Community Clinical Oncology and Prevention Trials Research Group) Program Analyst uses CTEP-ESYS (Cancer Therapy Evaluation Program Enterprise System) to check the status of studies. She also uses CTEP-ESYS to verify and update information in the CDUS (Clinical Data Update System) database. PIMS (Protocol Information Management System) will use the primary grant number to track U10 and R01 grants. For Contracts, PIMS will record the contract number, date of award, performance, and the end date. PIMS will accommodate outside sources of funding by providing an open text field for the source and a comments field for the details. Even though research bases and individual CCOP clinics receive DCP funding credits, PIMS will only track credit awards to the lead organization (i.e. the research base). The PIO staff will manually enter accrual information. High-level discussions are needed to help coordinate the sharing of accrual information when the study is funded by an R01 grant.

CTEP-ESYS and the CCOP Program Analyst

The Community Clinical Oncology and Prevention Trials Research Group (also called CCOP) Program Analyst uses a variety of data sources. The Cancer Treatment Evaluation Program Enterprise System (CTEP-ESYS) is one source of data. The Program Analyst uses CTEP-ESYS chiefly for three purposes. Figure 1 summarizes the types of use.

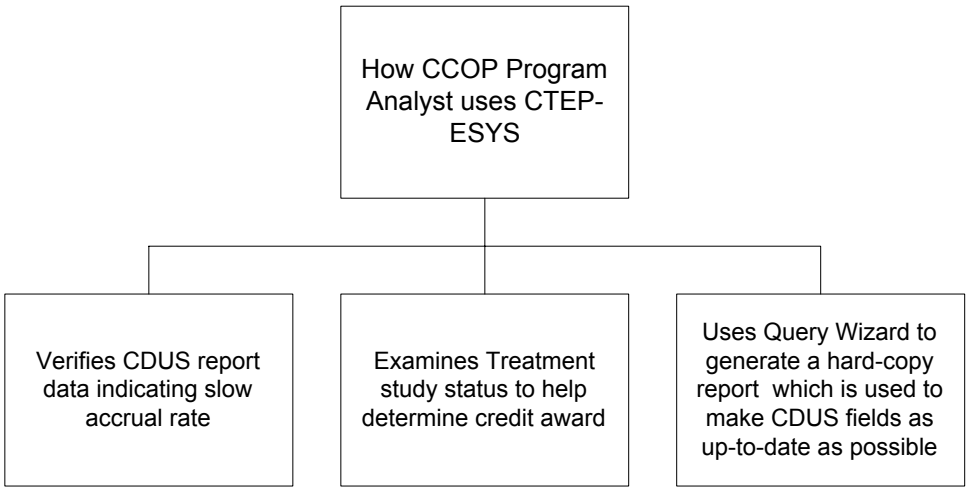

Figure 1: Three ways the CCOP Program Analyst uses CTEP-ESYS

Future versions of the Protocol Information Management System (PIMS) could contain a link to CTEP-ESYS. High-level discussions are needed to coordinate the sharing of data.

Verifying Clinical Data Update System Report

The Program analyst uses the Protocol Administration and Tracking System (PATS) in CTEP-ESYS when a rate of accrual reported in the Clinical Data Update System (CDUS) seems questionable. She verifies the CDUS data by comparing it with the PATS data.

Checking Study Status

Occasionally, staff from a CCOP will ask the Program Analyst why they have not received funding via a credit. CTEP's Protocol and Information Office (PIO) might not have sent the required data to the Analyst, thus delaying the credit award. In this case, the Analyst will use the PATS tool to check the study's status. If the data is correct, the CCOP will be awarded the credit.

Updating CDUS Fields

The Program Analyst will use the PATS tool to generate a report of up-to-date study information. She checks the corresponding data in CDUS and updates the fields accordingly.

Funding by Grants

The Protocol Information Management System (PIMS) will use grant numbers to track R01 (Modular Research Grant Application) grants and U10 (Cooperative Clinical Research) cooperative agreements. The U10 grant number will serve as a link in PIMS to other study information such as patient accrual and Principal Investigator (PI) contact data.

Primary and Secondary Grant Identification

Occasionally, A U10 agreement receives supplemental grant funding. In cases where this occurs, PIMS will use the primary U10 number.

A U10 number with the suffix "S" indicates supplemental funding. The protocol does not contain either the primary or secondary U10 number. Protocol Information Office (PIO) staff will rely on completed cover sheets or Community Clinical Oncology and Prevention Trials Research Group personnel to identify the appropriate U10 number.

Grant Extensions

U10 grants are generally awarded for five years. Grants may be extended for five-year periods after the initial five years expire. Each extension retains the original U10 grant number and accrual data is recorded consecutively.

Cooperative group chairs often serve as the grant PI throughout the life of the grant. Grant PIs change infrequently.

One Group With Two Grants

Cooperative research groups may receive separate U10 grants to pay for the operation of the trial and for statistical analysis of the study's data. Figure 2 shows a normal U10 Grant situation and one where the group receives two U10 Grants.

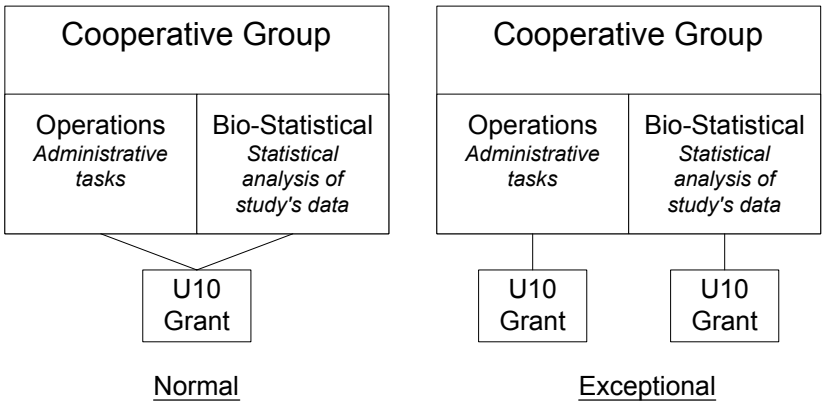

Figure 2: Normal U10 Grant Award and exception where the Research Group receives two U10 Grants

Both components are usually funded under one grant number. PIMS will track the operations office U10 grant because patient accrual is collected under that component. PIMS will not track the Bio-Stat U10 grant.

Cooperative Group Mergers and Grants

Recently, the groups of Children's Cancer Group, Intergroup Rhabdomysarcoma Study Group, the National Wilm's Tumor Study Group, and the Pediatric Oncology Group merged to form one cooperative group: Children's Oncology Group (COG).

PIMS will retain each group's separate grant number until new grants are awarded to the COG as a whole. PIMS will accommodate future cooperative group mergers the same way.

Funding by Contracts and Outside Sources

The Protocol Information Management System (PIMS) will not be the official source for contract information. The National Institute of Health's (NIH) Data Warehouse includes contract information, but the data is not up-to-date. The Contracts Office will serve as the main source of contract information for PIMS. Further KA is required to discover how PIMS will get information from the Contract Office.

PIMS should include a basic set of contract-related data important to Division of Cancer Prevention (DCP) Medical Monitors and Protocol Information Office (PIO) personnel:

- Contract number
- Date of award (document milestones)
- Period of performance
- End date

The official period of performance begins on the date the first patient is accrued.

Sources of Funding from Outside the DCP

PIMS will track sources of funding from outside the DCP (e.g. funding from a private foundation). The CCOP Program Analyst will use the outside funding information to see if a research base is receiving two sources of funding for the same component of the study.

PIMS will contain an open-text field for outside sources of funding (e.g. funding via a private foundation). A comments field will provide a place for details about the outside funding source.

DCP contract numbers are currently being tracked in the CCS Associates database Principal Investigator Track (PITRACK).

Credits

The overall Community Clinical Oncology Program is made up of numerous local community clinics called CCOPs. Each CCOP is affiliated with a particular research base. The research bases design the studies and perform most of the data management for its

CCOPs. Many of the research bases are Cooperative Groups, and the term "group" is sometimes used to refer to a research base.

Types of Credits

Credits are a form of funding for Community Clinical Oncology Program studies. The volume of data management involved in a study determines the amount of credits awarded. There are three types of credits:

1. Treatment Credit
2. Control Credit
3. Follow-up credit

Studies with a treatment or cancer control credit may receive follow-up credits. All Chemoprevention studies are assigned an initial credit for the first year a patient receives intervention. A certain amount of follow-up credit is awarded for each additional year of intervention. Large prevention trials sometimes receive an additional couple of years of follow-up credit beyond the time when the intervention has stopped.

A protocol many receive one of the following permutations of credit award:

- Treatment credit only
- Treatment and Follow-up
- Control credit only
- Control and follow-up

A single protocol will never receive all three types of credits.

Tracking Credits

PIMS will record three pieces of information concerning credits:

1. The type of credit awarded
2. The number of credits awarded (not the actual dollar amount)
3. Whether the lead organization receives the credit

PIMS will record the lead organization that receives credits but not individual CCOPs receiving credits. PIMS will provide a yes/no flag at the document version level to indicate whether the lead organization can claim credits.

Credit Awards

Credits are awarded to a study, but are distributed to the research bases and CCOPs that conduct the study. There are three scenarios for awarding credits to research bases:

1. One research base – it is the Lead Organization and receives credit
2. One research base – it is the Lead Organization but receives no credit
3. Multiple research bases – only the Lead Organization receives credit

Lead Organization Receives a Credit

A lead organization is the research base that develops and administers a protocol. The individual community clinics (i.e. CCOPs) accrue patients and conduct the patient-level work of the study.

In a normal study, both the research base and the participating CCOPs receive credit to help pay for the cost of conducting the trial. Figure 3 illustrates the first scenario of credit award.

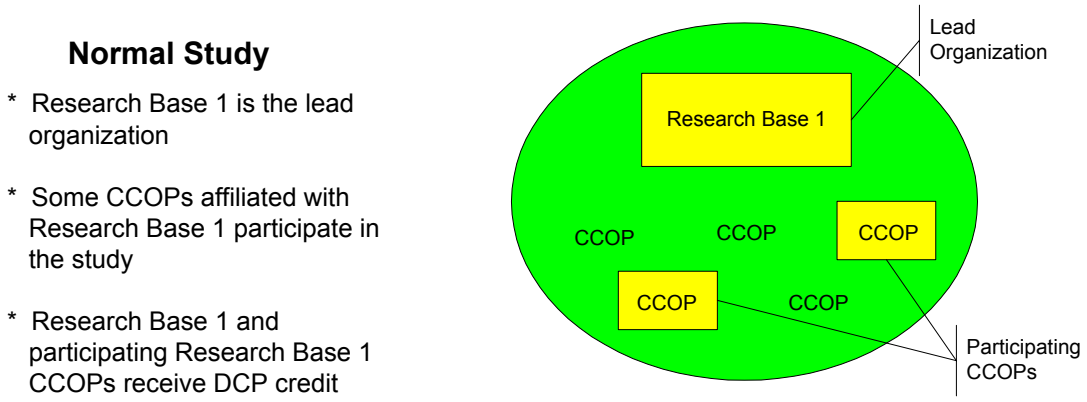

Figure 3: Scenario for Credit Award in a Normal CCOP Study

The oval shape contains a research base and its affiliated community clinics (CCOPs). The lightly shaded boxes indicate who receives credits.

Lead Organization does not Receive a Credit

There are two cases where a single research base may not receive credit. Both cases involve funding to the Research Base from sources other than credits.

The Research Base will sometimes receive funding for data management from a contract or R01 grant. In this case, only the participating CCOPs would receive credit because the Research Base is already funded for data management.

Occasionally, a CTEP treatment trial will be funneled through the DCP CCOP program. In this case, the Research base receives funding for data management from CTEP. The Research Base may not claim DCP credit in either case. Figure 4 illustrates these cases.

Dual Funding / Treatment Studies

* Research Base 1 is the lead organization but receives data management funding from a Contract, an R01 Grant, or from CTEP (for treatment studies funneled through the CCOPs)
* Some CCOPs affiliated with Research Base 1 participate in the study
* Participating Research Base 1 CCOPs receive DCP credit
* Research Base 1 does not receive credit

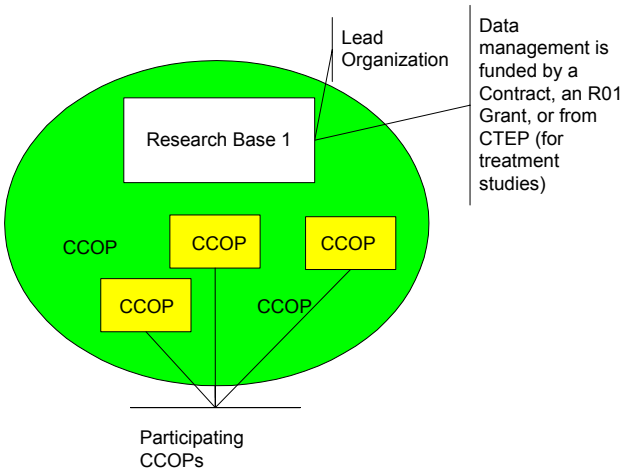

Figure 4: Scenarios for When a Lead Organization Does Not Receive Credit

The oval shape contains a research base and its affiliated community clinics (CCOPs). The lightly shaded boxes indicate who receives credits. The un-shaded box denotes a Research Base that is not receiving DCP credits.

Multiple Research Bases and Credit Award

Some studies are conducted using multiple research bases. These are called intergroup studies. Intergroup studies are an important means to avoiding redundancy in study design among Research Bases and for meeting large-size accrual goals.

Intergroup studies still have a lead organization with its participating CCOPs. However, CCOPs affiliated with other research bases are invited to participate in the lead research base's study. In this case, the participating CCOPs receive credit, but their research base does not.

Figure 5 shows this scenario using two research bases as an example. Actual intergroup studies can involve multiple research bases.

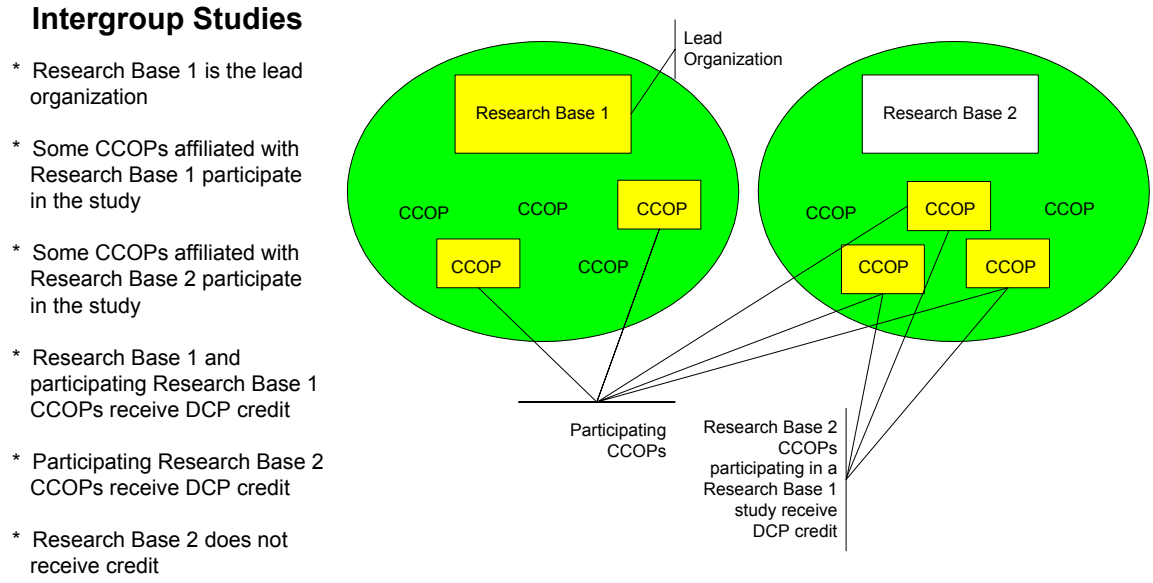

Figure 5: The Intergroup Scenario

The oval shape contains a research base and its affiliated community clinics (CCOPs). The lightly shaded boxes indicate who receives credits. The un-shaded box denotes a Research Base that is not receiving DCP credits.

Patient Accrual

Sources of Accrual Information

PIO personnel will populate PIMS with accrual data obtained from numerous sources. The information will be obtained from:

- Master Agreement Holders
- Quarterly Progress Reports submitted by Principal Investigators (PI)
- Abstracts from CCS
- Discussions with Clinical Research Associates and PI
- Clinical Data Update System (CDUS) reports

CDUS' accrual information has been "sanitized" to preserve the anonymity and privacy of each patient. The Operations Office of the Cooperative Group provides CDUS with:

- Patient ID number
- Patient's first name and last initial
- Patient's birth date
- Five-digit zip code

However, PIMS will only record high-level accrual information. PIO personnel will manually enter the following accrual data:

- Source of information

- Date of entry into PIMS
- Total number of accrued patients to date
    - Broken out by race and gender

Race and Gender Categories

PIMS will categorize accrual data by race and gender to help the PIO staff answer queries. Medical Monitors' data requirements should determine the degree of statistical breakout. However, the variation of patient eligibility in cancer prevention trials makes it hard to compile a list that would be inclusive of all the Medical Monitor's requirements.

Medical Monitors will still be able to consult CCS and CDUS for their data needs. Future versions of PIMS could include race and gender codes for each DCP Research Group.

PIO personnel will derive race and gender information from the CCS Progress Report and the CTEP Protocol Worksheet. PIMS will use a super-set of the two sources unless they are vastly different.

R01 Grants and Accrual

CCOP studies are occasionally funded by an R01 grant. Accrual information for a study funded by an R01 is reported in the R01 progress report. PIO personnel would prefer to abstract an R01's accrual information from the CDUS report.

High-level discussions at the NCI are required to help coordinate the sharing of this data.